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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,506	10/17/2001	Gregory R. Chiklis	19383-014	6911

7590 09/22/2004  
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EXAMINER PARK, HANKYEL	
ART UNIT	PAPER NUMBER

1648

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/981,506

Applicant(s)

CHIKLIS ET AL.

Examiner

Hankyel T Park

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-48, 65, 66, 68 and 69 is/are allowed.
- 6) ☒ Claim(s) 2-33 and 49-63 is/are rejected.
- 7) ☒ Claim(s) 14, 16, 28, 64 and 67 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

Claims 2-69 are pending and are examined.

Claims 14, 16, 28, 64 and 67 are objected to. Examiner believes Claim 28 should depend from claim 18 instead of claim 19. Claims 14, 16, 64 and 67 are objected to for depending from cancelled claim 1. Claims 14 and 16 should be amended to depend from claim 2. Claims 64 and 67 should be cancelled in view of claims 65 and 68.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-33 and 49-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horowitz, U.S. Patent 4,613,501 (Ref. A1) and Barbour et al., U.S. Patent 5,777,095 (previously cited; see Office Action of March 24, 2003).

Claims 2-33 and 49-63 of the instant application are directed to microorganism comprising surface proteins and substantially intact nuclear components, wherein one or more surface proteins have been irreversibly modified such that the microorganism is thereby rendered non-pathogenic. Claims 12-18, 49 and 60-63 are directed to modification in general, i.e. encompassing both by covalent attachment and by enzymatic digestion. Claims 2-9, 19-27, 30-33 and 50-57 are directed to modification by covalent attachment and claims 10-11, 28-29 and 58-59 are directed to modification by at least partial digestion by an enzyme. These claims do not mention the intended use language, i.e. for use as a control material, and even if they were to include such

language, not much weight would be given in determining the patentability of the claims. That being said, claims 2-33 and 49-63 are obvious over the prior art cited above for the reasons as follows:

Claims 2-9, 12-27, 30-33, 49-57 and 60-63 are rejected as being unpatentable over Horowitz. Horowitz teaches inactivation of a purified microorganism such as hepatitis B virus by an aldehyde, such as formaldehyde, or a dialdehyde, such as glutaraldehyde, to obtain non-pathogenic microorganism (col. 1, lines 25-58).

Claims 10-18, 28-29, 49 and 58-63 are rejected as being unpatentable over Barbour et al. Barbour teaches inactivation of a purified microorganism by any suitable manner, e.g. enzymatic, to obtain non-pathogenic microorganism (col. 19, lines 21-63).

Although Horowitz and Barbour do not include all of the viruses and intracellular parasites that have been listed in the instant application, one of ordinary skill in the art at the time the invention was made would have no problem of substituting the prior art's microorganism with any other microorganism for the purpose of obtaining non-pathogenic microorganism for any use requiring modified surface proteins whether the nuclear components are substantially intact or not, lacking any evidence to the contrary.

Claims 49-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horowitz, U.S. Patent 4,613,501 (Ref. A1) and Barbour et al., U.S. Patent 5,777,095 in view of Andrieu et al., U.S. Patent 5,552,269 (Ref. A4).

Horowitz and Barbour are as explained above. Andrieu teaches the use of inactivated viruses as a positive control in quantitation of retroviruses (col. 4, lines 52-63 and claim 1). The kit claims 49-63 recite a kit comprising a "positive control composition

comprising a purified sample of said microorganism” which is not a part of the biological sample to be tested. Applicant's “positive control” language, as broadly interpreted, encompasses Andrieu's “reference to a standard curve” language in claim 1.

Examiner would like to point out that the latter prior art was discussed in the Office Action of September 23, 2003 and that the Applicants have traversed the rejection mainly by arguing repeatedly that Barbour (patent ‘095) does not teach “production of a control material” (page 12, third paragraph). Although this Examiner withdrew the rejection under Barbour in the final office action of December 16, 2003, this rejection is again made in this office action upon further review of the claim language directed to a purified microorganism with certain modifications, which is taught in the prior art.

Claims 34-48 and 64-69 are, however, deemed to distinguish over the prior art because the claims are directed to a method comprising coamplification or addition of a positive internal control in the biological sample.

Claims 14, 16, 28, 64 and 67 are objected to for the reasons stated above.

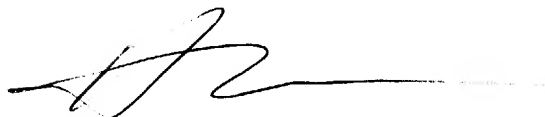
Claims 2-33 and 49-63 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hankyel T. Park whose telephone number is 571-272-0907. The examiner can normally be reached between 8:00 a.m. -2:00 p.m. on Mondays, 8:00 a.m. – 8:30 p.m. on Wednesdays, Fridays and Saturdays and 6:00 a.m. - 8:00 a.m. on Tuesdays and Thursdays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



HANKYEL T. PARK, PH.D.  
PRIMARY EXAMINER